APPARATUS AND METHOD FOR IMPLANTATION OF DEVICES INTO SOFT TISSUE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a Non-provisional application that claims the benefit of U.S. Provisional Application Ser. No. 61/690,044, titled APPARATUS AND METHOD FOR IMPLANTATION OF DEVICES INTO SOFT TISSUE, filed Jun. 18, 2012, which is incorporated by reference herein.

STATEMENT REGARDING FEDERALLY-SPONSORED RESEARCH AND DEVELOPMENT

This invention was made with partial government support under DARPA grant N660011114025. The government has certain rights in this invention.

FIELD OF THE INVENTION

The invention relates to apparatus and methods for the surgical implantation into soft tissue of devices, such as (1) prosthetic neural interfaces between computers and the machinery they control and biological tissue, for example neurons and the nodes of Ranvier on axons in nerve bundles, (2) optical fibers for the localized stimulation of neurons and other cell types, and (3) drug delivery catheters, among others. The micrometer-scale interfaces being surgically implanted can be used for recording from the soft tissue in which they are embedded or stimulating the soft tissue in which they are embedded. The invention relates to the accurate and minimally invasive placement of prosthetic micron-scale implants at a predetermined depth, location and orientation based on the profile of the tissue, for example the vasculature of the brain, and the use of implantation-specific data like soft tissue compression force prior to penetration and frictional force between the micrometer-scale implant and the tissue after penetration to optimize final placement of the interface. The invention relates to the use of ultrasonic oscillatory motions superimposed on the main trajectory to tailor the trajectory of the implantation to realize the reduction in insertion forces and soft tissue compression, which prevents effective insertion and increases tissue damage. The invention relates to the use of multi-unit cartridges for the implantation of multiple micrometer-scale interfaces during a single surgery without retooling, to reduce surgery time and minimize the handling of the prosthetic interfaces. The invention also relates to precise control of insertion speed, and tools for visual and sensor-based inspection of insertion characteristics such as initial tissue contact and forces during insertion.

BACKGROUND OF THE INVENTION

Many implantable devices that interact with tissue, including those used in surgical procedures, in-vitro tests, and in-vivo implantations, require special care for accurate positioning (location and orientation) of the implantation device. Furthermore, a critical issue is to ensure that implantation occurs satisfactorily; that is, the device is inserted in at the required depth without device failure. Manual insertions of devices cannot provide this level of control in positioning and insertion, therefore leading to high rate of device failure during insertion, over-design of devices with larger-than-needed foreign materials, and functional failures. An important need is to have automated mechanisms for insertion, that provide precision in positioning (cellular-scale, approximately 20 μm), orientation (±0.5), and speed control (±1%), as well as allow feedback and evaluation through visual and sensor-based in-situ characterization capability.

An illustrative example of this need arises from the insertion of the neural probes for brain-computer interfaces (BCI). Research on BCI and brain-machine interfaces (BMI) in recent years has demonstrated the feasibility of driving motor prostheses for the upper limbs of amputees and for restoring mobility to quadriplegics and tetraplegics whose condition arose due to injury or disease. More recently, research has begun to focus on providing feedback loops between the brain and other nervous tissue and the computers and machines to which they are interfaced by stimulating the tissue with signals from the external equipment to return sensation to BMI and BCI recipients. In this way, an injured or diseased individual can control an external prosthetic and receive sensation from it in a way that naturalistically mimics the limb they lost or the biological function that is impaired.

BCIs and BMIs comprise: 1. an interface to the soft tissue that records the electrical, chemical or mechanical activity of the soft tissue and transduces it to a signal in a suitable energy domain, typically electrical, 2. a decoder that extracts the information from the signals received from the tissue, 3. a transmitter that sends out the decoded signals, 4. a receiver of the decoded signal, 5. a computer or machine that acts under the instructions carried in the decoded signals, 6. a sensor array that detects changes in the environment caused by the action of the computer or the machine and transduces it to a signal in a suitable energy domain, 7. an encoder that receives the output of the sensor array and converts it to a sensory signal for transmission, 8. a transmitter that sends out the encoded sensory signals, 9. a receiver of the encoded sensory signals, and 10. an interface that transduces the encoded sensory signals to an electrical, chemical or mechanical signal for stimulation of the soft tissue in which the interface is embedded.

The interface is a critical feature of BMIs and BCIs and its placement must be as close as possible to the biological signal sources without damaging them in order to maximize the information extracted from the soft tissue and minimize the amount of energy needed to transmit sensory information back into the soft tissue. The most common interface is the electrode. Typically, this is an insulated, electrically conductive material with a small surface exposed to the soft tissue environment. Electrodes have dimensions ranging from 10s of micrometers to 100s of micrometers. The effectiveness, stability and reliability of these interfaces has been identified in the literature, in part, as dependent on the method of implantation and the accuracy of their placement. Interface reliability is a critical research area where progress is needed prior to transitioning BMI and BCI technology for practical restoration of motor and sensory functions in humans. Two key issues are 1) the inability of current interfaces to reliably obtain accurate information from tissue over a period of decades, and 2) currently measured signals from tissue cannot be reliably used to control high degree-of-freedom (DOF) prostheses with high speed and resolution.

Failure of biological soft tissue interfaces may be caused by several issues. After implantation, current probes are surrounded by reactive microglia and reactive astrocyte scarring as shown pictorially in FIG. **1**(*a*). In the brain, damage to the neural vasculature causes a breach in the blood-brain barrier (BBB) that is associated with reactive soft tissue responses. Tissue reaction with the probe results in encapsulation that insulates the electrode by impeding diffusion of chemical and